UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHRISTEL BILLHOFER, On Behalf of Herself and All Others Similarly Situated, Plaintiff, vs. FLAMEL TECHNOLOGIES, SA, et al., Defendants.	Civil Action No. 1:07-cv-09920-CSH CLASS ACTION AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS **DEMAND FOR JURY TRIAL**

Lead Plaintiff Christel Billhofer ("Lead Plaintiff" or "Plaintiff") makes the following allegations based upon the investigation undertaken by her counsel, which included analysis of publicly available news articles and reports, public filings, securities analysts' reports and advisories about Flamel Technologies, SA. ("Flamel" or the "Company") and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all purchasers of the American Depository Receipts ("ADR") of Flamel between March 23, 2007 and August 22, 2007 (the "Class Period") against Flamel and certain of its officers and directors for violations of the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The claims asserted arise under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Jurisdiction is conferred by Section 27 of the Exchange Act. Venue is proper pursuant to Section 27 of the Exchange Act. Flamel's headquarters are located in Venissieux, France. The Company conducts business in this District and its ADRs trade on the NASDAQ, which is located in this District.

PARTIES

3. Plaintiff Christel Billhofer purchased Flamel ADRs during the Class Period, as set forth in her certification which was previously filed in this case and is incorporated by reference herein, and was damaged thereby.

4. Defendant Flamel's headquarters are located in Venissieux, France. Flamel's ADRs are traded under the symbol FLML on the NASDAQ, an efficient market. Flamel is a

biopharmaceutical company which develops polymer-based delivery technologies for medical applications.

5. Defendant Stephen H. Willard ("Willard") was, at all relevant times, the Chief Executive Officer of Flamel.

6. Defendant Rafael Jorda ("Jorda") was, at all relevant times, Chief Operating Officer, Executive Vice President and Director of Manufacturing and Development of Flamel.

CLASS ACTION ALLEGATIONS

7. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Flamel ADRs during the Class Period. Excluded from the Class are Defendants and the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

8. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Flamel ADRs were extensively traded over the NASDAQ and Flamel had 23 million ADRs outstanding, owned by thousands of persons.

9. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class, which predominate over questions which may affect individual Class members, include:

(a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) Whether Defendants' statements issued during the Class Period were materially false and misleading when issued; and

(c) The extent of damage sustained by Class members and the appropriate measure of damages.

10. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

11. Plaintiff will adequately protect the interests of the Class and has retained counsel that is experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

12. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

SUBSTANTIVE ALLEGATIONS

The Company and its Business

13. Defendant Flamel develops polymer-based delivery technologies for medical applications. The Company specializes in helping pharmaceutical companies develop extended release drugs.

14. Flamel's lead product is COREG CR (controlled release) which is used in the treatment of moderate to severe congestive heart failure, left ventricular dysfunction following myocardial infarction and hypertension. COREG CR was introduced by Flamel and its marketing partner GlaxoSmithKline ("GSK") in March 2007.

15. Prior to the introduction of COREG CR, GSK marketed and sold COREG IR, which required users to take one pill twice-a-day while COREG CR is only required to be taken once-a-day. The successful introduction of COREG CR was critical to GSK and Flamel as the companies needed to transition users to COREG CR from COREG IR before generic competition entered the market, which was expected to occur in late 2007.

16. Flamel and GSK promoted COREG CR as an improved and better version of COREG IR because it was only required to be taken once-a-day. It is widely known that a primary issue for users of cardiac medication is compliance, as users of this type of medication have a high incidence of failing to take the required dosage of the medication.

17. By at least the start of the Class Period, however, Defendants knew, or recklessly disregarded, that a clinical study conducted by Flamel and GSK had concluded that COREG CR is not better at encouraging compliance with recommended dosage instructions than COREG IR. In other words, there was no compliance benefit by switching from COREG IR to COREG CR.

Flamel Fails to Timely Disclose Results from Clinical Trial that Concluded that Use of COREG CR Does Not Improve Pill-Taking Compliance

18. In order to prove the benefits of COREG CR, GSK and Flamel commenced a clinical trial to measure the differential compliance, quality of life and satisfaction with medication in chronic heart failure patients taking COREG IR vs. COREG CR (the "CASPER Trial"). The primary outcome of the CASPER Trial was pill-taking compliance.

19. By no later than the start of the Class Period, the CASPER Trial was complete and the results were made known to GSK and Flamel. An abstract of the CASPER Trial was required to be submitted to the *Journal of Cardiac Failure* by no later than April 9, 2007. To meet this deadline, GSK and Flamel were required to complete the CASPER Trial, analyze the associated data, and draw conclusions therefrom – all sufficiently in advance of the submission date.

20. The abstract of the CASPER Trial, which was submitted to the *Journal of Cardiac Failure*, concluded that switching from COREG IR to COREG CR "was not associated with better drug taking compliance. . . ." **Thus, the primary selling point for COREG CR was not supported by the CASPER Trial.**

21. As detailed further herein, when the abstract of the CASPER Trial was published in the *Journal of Cardiac Failure*, on or about August 23, 2007, the price of Flamel ADRs plummeted in response. Defendants, however, had known, or recklessly disregarded, the conclusions of the CASPER Trial for five (5) months and failed to disclose them to investors.

Materially False and Misleading Statements Issued During the Class Period

22. The Class Period commences on March 23, 2007. On that date, Flamel issued a press release announcing the nationwide availability of COREG CR. With respect to the product introduction the press release stated in pertinent part as follows:

> Flamel Technologies is pleased that GlaxoSmithKline yesterday announced the U.S. nationwide availability of COREG CR™ (carvedilol phosphate) extended release capsules for use in treating three cardiovascular conditions:
>
> - High blood pressure, also known as hypertension;
> - A heart attack that reduced how well the heart pumps (known medically as post-myocardial infarction left ventricular dysfunction); and
> - Mild to severe heart failure.
>
> COREG CR™ microparticles are produced by Flamel Technologies at its production facility in Pessac, France, using the company's MICROPUMP® technology platform.

Defendant Willard commented on the announcement stating in pertinent part as follows:

> We are pleased that COREG CR™ will now be available to patients in the U.S. for the treatment of these three serious conditions. COREG CR™ is the first marketed product incorporating Flamel's MICROPUMP® technology. The success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology as well as in our MEDUSA® technology platform for the delivery of proteins and peptides. Interest in both technologies has never been higher.

23. On April 30, 2007, Flamel filed with the Securities and Exchange Commission its Form 20-F Annual Report for the fiscal year ended December 31, 2006, which was signed by

Defendant Willard (the "2006 Form 20-F"). With respect to revenues associated with sales of COREG CR, the 2006 Form 20-F stated in pertinent part as follows:

> We also expect an increased revenue stream from royalties as a result of the approval and launch of Coreg CR by GlaxoSmithKline in the first quarter of 2007, which marks the first commercial utilization of Flamel's Micropump technology.

24. On May 7, 2007, Flamel issued a press release announcing its financial results for the first quarter of 2007. For the quarter, the Company reported revenues of $9.6 million. Defendant Willard commented on the results, stating in pertinent part as follows:

> We are pleased with the early success of the COREG CR launch. Feedback from the cardiological community has been very positive. Physicians understand that the once-daily formulation of COREG CR offers key advantages to patients. **It is well established that once-daily medications lead to greater patient compliance; non-compliance is one of the leading causes of hospitalization in heart failure patients.** COREG CR delivers substantially the same peak and trough levels of carvedilol as the twice-a-day drug, taken as directed, but with a smoother release profile. Moreover, COREG CR has been observed to result in 24% fewer adverse events than immediate release Coreg in a crossover study conducted in hypertension patients. The success of COREG CR is generating positive interest in the Micropump platform from potential partners and interest in the Medusa® platform has also been renewed. We look forward to further positive developments with both platforms during 2007. [Emphasis added.]

25. Also on May 7, 2007, Flamel held a conference call with analysts and investors to review its first quarter financial results and operations. During the conference call, Defendant Willard highlighted the compliance issue as it relates to COREG CR, stating in pertinent part as follows:

> First of all, there is the compliance issue, which should not be ignored. According to a study of more than 3,000 patients, 64% of hospitalizations for heart failure was linked in the study to non-compliance with prescribed medicines. But, additionally, COREG CR provides a smooth, 24-hour release profile and an average of 16% more drug in the body over a 24-hour period.

During the conference call, Defendant Willard was directly asked about data from ongoing clinical trials of COREG CR. The following exchange took place:

Matt Kaplan - Punk, Ziegel & Company – Analyst:

Okay, and just one last question on COREG. When do you expect the data from the ongoing trials you mentioned to become available and/or published, either announced in top-line form or published?

Stephen Willard - Flamel Technologies – CEO:

I think there's a lot of data coming through. I mean, if you look at clinicaltrials.gov, if you look at a variety of other sources, you can see that there's a lot of data working through the system.

It will be within GSK's call as to how that data comes out. They typically like to release data around some of the important meetings that occur throughout the year, but it will be for GSK to be able to talk about the timing of some of the studies. You've got the CASPER study, you've got the COMPARE study, you've got a number of head-to-head stuff. You've got studies with regard to combination products.

There's a lot of things moving through the pipeline, and GSK will, I think, get those out appropriately, probably, and I'm just guessing here, in connection with some of the major conferences that will occur over time.

26. On August 1, 2007, Flamel issued a press release announcing its financial results for the second quarter of 2007. For the quarter, the Company reported revenues of $7.4 million. Defendant Willard commented on the results, stating in pertinent part as follows:

> Flamel has recently entered into further new relationships for its Medusa platform . . . . We believe that further potential agreements for other molecules are progressing well and that we are creating a diversified set of opportunities for our Medusa platform. The Phase I clinical trial on the new formulation of Basulin, our long-acting basal insulin, has commenced, and we continue to expect that it will be completed by the end of the third quarter. Regarding COREG CR, we believe it has strong ongoing potential in all indications. We continue to manufacture at the maximum rate and expect to do so even after the addition of new manufacturing capacity.

27. On August 2, 2007, Flamel held a conference call with analysts and investors to review its second quarter financial results and operations. During the conference call, Defendant Willard directly commented on the CASPER Trial but failed to disclose the adverse conclusion of that study. The following exchange took place:

Matt Kaplan – Punk, Ziegel and Co – Analyst:

And you mentioned one aspect of that is additional clinical data. One of the trials that you're talking about is, I guess, potentially, the CASPER study, which is an IR versus CR trial. When do you expect the data from that to be presented? GSK has indicated previously that it could be in the third quarter of this year. Do you have any sense in terms of where that could be presented?

Stephen H. Willard – Flamel Technologies – CEO:

I – That's for GSK to be able to tell people about.

28. The statements referenced above in ¶¶22-27 were materially false and misleading when issued as they failed to disclose that the CASPER Trial was completed and had concluded that switching from COREG IR to COREG CR was not associated with better drug-taking compliance. Defendants' positive statements about COREG CR created an obligation to disclose the adverse conclusion of the CASPER Trial which materially undermined Defendants' claims about the positive attributes of the Company's proprietary technologies.

The Truth Is Revealed

29. On August 23, 2007, *Associated Press* published an article entitled "Flamel Technologies Shares Dive on Disappointing Coreg Study Results," which stated in part:

Shares of Flamel Technologies plunged Thursday after a study of its once-daily heart disease drug failed to show any benefit over the twice-daily version.

The study results, published in the Journal of Cardiac Failure, showed that Coreg CR, which was launched March 22, was similarly effective as Coreg IR, the twice-daily version of the drug.

Shares of the Lyon, France-based biopharmaceutical company plunged $3.12, or 24.6 percent, to close at $9.56. The stock reached a 52-week low of $8.96 during the regular trading session.

"As a result, we believe formulary adoption of Coreg CR will be hindered in the near-term, limiting potential growth of Coreg CR prescriptions," said Merriman Curhan Ford analyst E. Russell McAllister.

30. On this news, Flamel's ADR price dropped from $12.68 to $9.56 per share on extremely heavy trading volume.

31. On August 24, 2007, *Motley Fool* reported the following in an article entitled "Flamel Under Fire":

> There's no sector more volatile than the pharma sector as Flamel Technologies has proven in the past three months. Shares of the tiny drug developer have fallen 65% since the beginning of June and were down more yesterday after unfavorable data was released on its lead drug, heart failure treatment Coreg CR.
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> * * *
>
> Unfortunately for GSK and Flamel, the study showed that patients taking Coreg CR did not comply with usage regimens at a higher level than those taking the twice-a-day version. (This study was designed to be part of a one-two punch by GSK in conjunction with the ongoing COSMOS hypertension study, which is trying show that Coreg CR is superior to AstraZeneca's Zestril.)
>
> One of the reasons Flamel and GSK ran the clinical trial that was written about yesterday was because previous studies had shown that up to 64% of hospitalizations related to heart failure were due to patient noncompliance with their medication. The obvious consequence of the unfavorable journal article is that Coreg CR may be slightly harder to market, and doctors may be more reluctant to prescribe it. This likely isn't the major issue, though.
>
> **The problem with journal articles such as these is that they give ammunition to insurance companies to cover less of the drug's costs or not pay for it at all. If insurers find the extra benefits of Coreg CR to be hazy, they will grant it less favorable coverage versus its generic immediate-release counterparts.** This then means that insured patients would have to pay more out-of-pocket expenses if they want the convenience of a once-a-day pill, and also that GSK would be able to charge less of a premium for Coreg CR.
>
> As Flamel has mentioned in the past, there are four areas of potential growth for the use of Coreg CR: patients switching from the IR version, using the drug in combination with other therapies, proving its broader use (a hypertension study is ongoing), and selling it internationally.
>
> **Investors shouldn't take this journal article to mean the end of Coreg CR's potential as a blockbuster (there's still the important COSMOS study, for example) but it's certainly bad news in near and intermediate terms until GSK puts out new positive data on the drug.** [Emphasis added.]

32. On August 27, 2007, *Motley Fool* reported the following in an article entitled "Flamel Falls Out of Compliance":

Well, *this* is a bitter pill for Flamel investors to swallow. A study released last week showed that the biotech's technology allowing once-a-day dosing of GlaxoSmithKline's Coreg CR is no better at encouraging compliance than the twice-a-day regimen patients followed with the original version of Coreg.

The market walloped the stock once again, cutting its value by nearly one-fourth last week. Flamel's stock is down 75% from its 52-week high.

Flamel investors had hoped that a commercial success from the application of its drug delivery technology to Glaxo's blockbuster beta-blocker Coreg would light a fire with other drug companies to sign on the dotted line. Sanofi-Aventis, for example, had captured about 30% of the market for its extended-release version for Ambien. In the past, Flamel has had deals with Biovail and Bristol-Myers Squibb, but the company's been glacially slow to seal new agreements.

Adding to the pessimism, Glaxo ran into problems with another of its drugs, Avandia, and turned its attention away from Coreg CR. It then reported that conversions to the new formulation weren't what it hoped, though it said it would be giving Coreg CR renewed focus in the weeks ahead. With generic versions of the original Coreg coming to market next month, Glaxo's window of opportunity to get patients onto its new CR program is quickly closing.

* * *

The current study does crimp Flamel's hoped-for revenue streams from Coreg CR. Right now, the drug is the only approved product using Flamel's technology, and thus the only one providing royalty revenue. Flamel's management has said it's in discussions with as many as four new partners to license its technology. Should any one of them come through, new revenue spigots could open.

Loss Causation/Economic Loss

33. During the Class Period, as detailed herein, defendants made false and misleading statements by means of concealment and obfuscation of critical clinical trial data and engaged in a scheme to deceive the market. This artificially inflated the price of Flamel's ADRs and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, Flamel's ADRs fell precipitously, as the prior artificial inflation came out. As a result of their purchases of Flamel ADRs during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

Additional Scienter Allegations

34. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly or recklessly substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Flamel, their control over, and/or receipt and/or modification of Flamel's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Flamel, participated in the fraudulent scheme alleged herein.

No Safe Harbor

35. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Flamel who knew that those statements were false when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

36. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's ADRs traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's ADRs; and

(e) Plaintiff and other members of the Class purchased Flamel ADRs between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

37. At all relevant times, the market for Flamel ADRs was efficient for the following reasons, among others:

(a) As a regulated issuer, Flamel filed periodic public reports with the SEC; and

(b) Flamel regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

COUNT I

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

38. Plaintiff incorporates ¶¶1-37 by reference.

39. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

40. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Flamel ADRs during the Class Period.

41. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Flamel ADRs. Plaintiff and the Class would not have purchased Flamel ADRs at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

42. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Flamel ADRs during the Class Period.

COUNT II

For Violation of Section 20(a) of the Exchange Act Against All Defendants

43. Plaintiff incorporates ¶¶1-42 by reference.

44. The Individual Defendants acted as controlling persons of Flamel within the meaning of Section 20 of the Exchange Act. By virtue of their positions and their power to control public statements about Flamel, the Individual Defendants had the power and ability to control the actions of Flamel and its employees. Flamel controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding plaintiff and the members of the Class damages and interest;

C. Awarding plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: March 27, 2008

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CERTIFICATE OF SERVICE

I, Samuel H. Rudman, hereby certify that on March 27, 2008, I caused a true and correct copy of the attached:

Amended Complaint for Violation of the Federal Securities Laws

to be: (i) filed by hand with the Clerk of the Court; and (ii) served by first-class mail to all counsel on the attached service list.

Samuel H. Rudman

FLAMEL
Service List - 1/7/2008 (07-0241)
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